UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York, Plaintiffs, v. QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation; QUINCY BIOSCIENCE, LLC, a limited liability company; PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC., Defendants.	Case No. 1:17-cv-00124-LLS

STIPULATION OF AGREED FINDINGS

Plaintiffs, the Federal Trade Commission and the People of the State of New York, by Letitia James, Attorney General of the State of New York (collectively, "Plaintiffs"), and Defendants, Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC, and Mark Underwood (collectively, "Defendants"), have met and conferred and, in an effort to streamline trial proceedings, hereby agree and stipulate to the following agreed facts:

1. Since 2007, Prevagen® has been available in several different sizes (Regular Strength, Extra Strength, and Professional), two different formats (capsules and chewable tablets), two different counts (30 and 60 count) and multiple and different types of packages (collectively, "Prevagen Products").

2. Prevagen Regular Strength contains 10 milligrams ("mg") of apoaequorin and is sold as capsules and chewables; Prevagen Extra Strength contains 20 mg of apoaequorin and is sold as capsules and chewables. When Prevagen Professional was initially made available for sale, it contained 20 mg of aequorin. In 2011, Prevagen Professional was reformulated to include 40 mg of apoaequorin.

3. Certain Prevagen Products (Regular Strength Capsules, Regular Strength Chewables, Extra Strength Capsules, Extra Strength Chewables, and Prevagen Professional) are currently available for sale in 30-count packages. Other Prevagen Products (Regular Strength Capsules and Extra Strength Capsules) are currently available for sale in 60-count packages.

4. Apoaequorin is a recombinant, fat insoluble protein composed of 196 amino acids with a molecular weight of 22.3kD (kilodaltons).

5. In or around 2016, Prevagen Products were reformulated to include 50 micrograms of vitamin D3 per capsule or chewable tablet, which is equivalent to 2000 IU of vitamin D.

6. Quincy Bioscience Holding Company, Inc., wholly owns: Prevagen, Inc., which markets Prevagen Products, oversees the manufacturing of Prevagen Products by a third party, and sells Prevagen Products to consumers, retailers, distributors and healthcare professionals nationwide; Quincy Bioscience Manufacturing, LLC; and Quincy Bioscience, LLC, the holder of Prevagen-related patents and trademarks.

7. Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Quincy Bioscience Manufacturing, LLC, and Prevagen, Inc. (collectively, "Corporate Defendants") share a common business address at 726 Heartland Trail, Suite 300, Madison, WI 52717.

8. Corporate Defendants share the same officers, including individual Defendant Mark Y. Underwood.

9. Underwood is the largest individual shareholder of Quincy Bioscience Holding Company, Inc. and is on the Board of Directors of Quincy Bioscience Holding Company, Inc.

10. Underwood came up with the idea to create Prevagen with the active ingredient apoaequorin based on independent research he did as a hobby while he was an undergraduate student.

11. Prevagen advertisements have been disseminated to consumers nationwide, including in the State of New York, through a variety of media, including television, radio, print, the internet, social media, product labeling and packaging, and press releases, including during the time periods shown in Exhibit A attached hereto.

12. Defendants have marketed Prevagen nationally on television since at least June 2013.

13. Testimonials from persons discussing the benefits of Prevagen have been available on a Prevagen Facebook page since at least November 11, 2020.

14. Quincy Bioscience, LLC sponsored the Madison Memory Study and conducted the study from 2009 to April 2011.

15. Each of the Madison Memory Study Papers describes the Madison Memory Study as having 218 participants (QUI-FTCNY-00100136 – QUI-FTCNY-00100146; QUI-

FTCNY- 00091501 – QUI-FTCNY-00091518; QUI-FTCNY-00003811 – QUI-FTCNY-00003818; QUI- FTCNY-00003696 – QUI-FTCNY-00003705).

16. The entire study population of the Madison Memory Study consisted of the participants who applied, were randomized, and completed the study, which amounted to 211 adults.

17. Participants in the Madison Memory Study completed the AD8 Dementia Screening Interview, an eight-question interview to differentiate adults showing normal cognitive aging from those experiencing cognitive impairment, with possible scores ranging from AD8 0 to AD8 8.

18. None of the Madison Memory Study participants were excluded based on their scores on the AD8 Dementia Screening Interview, and the study population included participants with scores above an AD8 2 on the AD8 Dementia Screening Interview.

19. The Madison Memory Study included administration of the following nine Cogstate tasks: (1) Groton Maze Learning ("GML"); (2) Groton Maze Learning – Delayed Recall ("GMR"); (3) International Shopping List ("ISL"); (4) International Shopping List – Delayed Recall ("ISRL"); (5) One Card Learning ("OCL"); (6) Two Back ("TWOB"); (7) One Back ("ONB"); (8) Detection ("DET"); and (9) Identification ("IDN").

20. Participants in the Madison Memory Study completed the Cogstate tasks at several intervals over 90 days (specifically, days 0, 8, 30, 60, and 90).

21. The Madison Memory Study had a rolling enrollment of participants.

22. The Madison Memory Study Protocol listed a sample size of 100.

23. The Madison Memory Study Protocol does not indicate the Study's Type I error rate.

24. The Madison Memory Study Protocol does not indicate how many, or which, Cogstate tasks will be administered in the Madison Memory Study.

25. The Madison Memory Study Protocol does not indicate that a composite score will be used for the Cogstate tasks.

26. The Madison Memory Study Protocol does not define clinical significance.

27. In the Madison Memory Study, all participants who are in the AD8 0-1 subgroup are also in the AD8 0-2 subgroup.

28. The Madison Memory Study researchers used a Type I error rate of p less than or equal to 0.05 to determine statistical significance.

29. The Madison Memory Study was not analyzed using a composite score for the Cogstate Research Battery.

30. The Madison Memory Study researchers analyzed the entire study population consisting of more than 200 adults, the AD8 0-1 subgroup, the AD8 0-2 subgroup, and the AD8 2-5 subgroup.

31. Defendants have not conducted any reported study on apoaequorin's effect on memory in a population of older adults with normal to mildly impaired cognitive function since the Madison Memory Study.

32. After the completion of the Madison Memory Study, neither Defendants, nor anyone acting on behalf of Defendants, have conducted any reported placebo-controlled human clinical study of apoaequorin or Prevagen using quantitative assessments of memory or other cognitive function in a population defined as, and limited to, adults with normal or mildly impaired cognitive function, with the exception of the Memory Improvement Trial ("MIT").

33. Defendants have not conducted any studies on the formulation of Prevagen with vitamin D.

34. Between approximately November 2008 and July 2009, Defendants conducted the Quality of Life ("QoL") Study, which was a 90-day randomized, double-blind, placebo-controlled study designed to measure the effect of apoaequorin on quality of life. Approximately 29 individuals who initially signed up for the QoL Study did not participate in or complete the study for a variety of reasons, the most common being that they were not in compliance with the study's protocol.

35. Between approximately May 2008 and January 2009, Defendants conducted an Open-Label Trial consisting of approximately 55 adult participants to assess the impact of apoaequorin on cognition, general health, and quality of life. The participants received 10 mg of apoaequorin per day for 90 days. There was no control group or blinding in the Open-Label Trial.

36. The Sunsho Pharmaceutical Study was a 15 person, open-label, unblinded study in which the subjects took 10 mg of Prevagen per day for 30 days.

37. Dr. Jeremy M. Berg testified that he does not have any reason to doubt that "it is known that the gut must communicate with the brain but the underlying neural circuits and transmitters mediating the gut-brain sensory transduction still remain unknown."

38. Richard Goodman, PhD, was the principal investigator and author of a report of a 2010 study evaluating the potential allergenicity of apoaequorin.

39. Following the enactment of the Dietary Supplements Health and Education Act of 1994 ("DSHEA"), the FTC issued "Dietary Supplements: An Advertising Guide for Industry" ("Guidance") "to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising."

40. The FTC issued the Guidance in 1998.

41. The Guidance is intended to help marketers understand how FTC law applies to the advertising of dietary supplements.

STIPULATED AND AGREED BY:

Dated: February 21, 2024

FEDERAL TRADE COMMISSION

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of February, 2024, I have caused service of the foregoing Stipulation of Agreed Findings to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: February 21, 2024

/s/ Tiffany M. Woo
Tiffany M. Woo
Federal Trade Commission